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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,845	10/17/2003	Antonella Pesce	CM2526C	9579

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EXAMINER

ARNOLD, ERNST V

ART UNIT PAPER NUMBER

1616

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,845

Applicant(s)

PESCE ET AL.

Examiner

Ernst V. Arnold

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 10-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/22/04 3/6/06 4/6/06

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

The Examiner acknowledges Applicant's election without traverse of Group II claims 10-12 drawn to an article. The Examiner requested an election of species for purposes of examination and upon further consideration is withdrawing the election of species. Applicant has cancelled claims 1-9 and added claims 13-20. Accordingly, claims 10-20 are presented for examination.

Comment: In claim 10, formula (II), R2 and R3 do not appear to have proper bond connectivity to the molecule. The Examiner suggests drawing the formula (II) such that there is an unmistakable bond between the oxygen atom and the variable.

Comment: Please remove the second period at the end of claim 10.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 14 and 16 recite "cyclohexyl derivatives" and claim 14 further recites "cyclohexanol derivatives". It is unclear to the Examiner if these are functional derivatives or structural derivatives. It is unclear to the Examiner how far one can modify cyclohexyl or cyclohexanol and still maintain function.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (US 6,506,958) in view of Hasegawa et al. (US 5,364,626).

Applicant claims a hygienic article comprising a composition comprising a cooling agent with an ester derivative.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Williams teaches a signal tampon with an indicator designed to provide a sensory signal to the user (Abstract). The sensory signal can be a cold sensation produced by such materials as menthyl lactate, menthol, ethanol or combinations thereof (Column 4, lines 1-10 and claim 16). It is the Examiner's position that the teaching of Williams

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suggests combining a first cooling agent, menthol, with a second cooling agent such as menthyl lactate.

Hasegawa et al. provide a teaching where esters of citric acid, such as triethyl citrate, are used to provide a sustained release effect for repelling materials on fibers (Column 2, lines 17-30; column 5, lines 60-64 and claims 1 and 2). Hasegawa et al. teach that certain repellants are menthol, spearmint oil, L-carvone, and camphor, for example (Column 2, lines 8-18).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

1. Williams do not expressly teach the signal tampon with an ester derivative.
2. Williams do not expressly teach the signal tampon with a first cooling agent and a second cooling agent in a weight ratio of 1/1 to 1/100.
3. Williams do not expressly teach the article wherein the composition is suitable for topical application to the external surface of a mammal in the form of a cream, lotion, emulsion, dispersion, gel, foam, oil, ointment or powder.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add an ester of citric acid, such as triethyl citrate, as

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suggested by Hasegawa et al. to the hygienic article, tampon, of Williams and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Hasegawa et al. teach that a cooling agent such as menthol can have prolonged release in the presence of compounds like triethyl citrate. One of ordinary skill in the art would want to add the triethyl citrate in order to increase the shelf life of the product.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to add a first cooling agent and a second cooling agent in a weight ratio of 1/1 to 1/100 to the composition of Williams and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Williams suggests combining cooling agents and it is merely routine optimization for one of ordinary skill in the art to arrive at the ratio of 1/1 to 1/100 by weight of the cooling agents.

3. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the article of Williams wherein the composition is suitable for topical application to the external surface of a mammal in the form of a cream, lotion, emulsion, dispersion, gel, foam, oil, ointment or powder.

One of ordinary skill in the art would have been motivated to do this because Williams teaches that the indicator can be in a hydrogel which is a type of gel (Column 3, lines 51-52).

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In the absence of any criticality/unexpected results, the presently claimed invention is considered *prima facie* obvious over the prior art for the reasons of record and those stated above.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

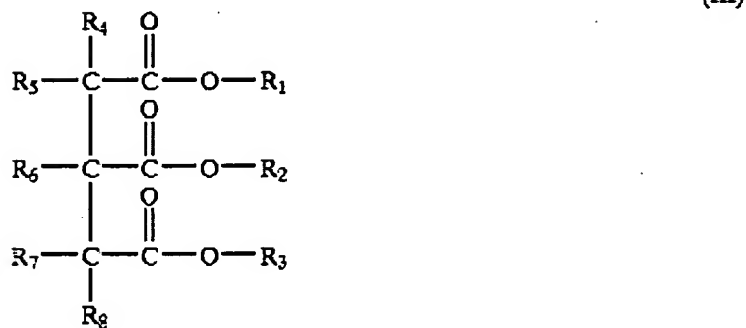
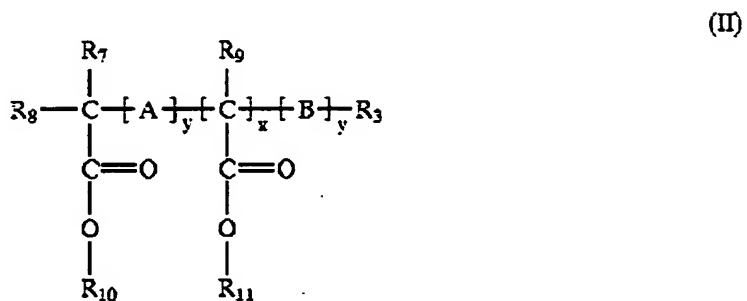
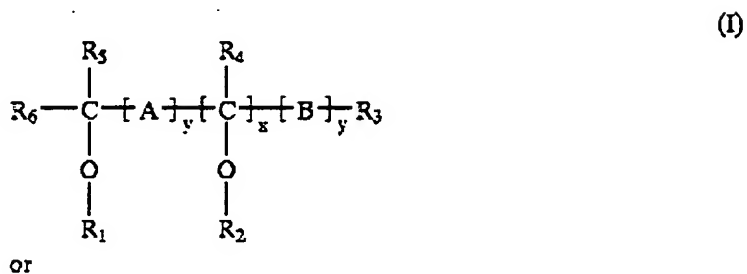
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-15 and 18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,972,010. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the instant application is embraced by the claimed subject matter in the patent.

Claim 1 of US 6,972,010 is drawn to an absorbent article comprising an agent able to convey a perception to the wearer and a delivery system for containing and delivering the agent to the skin. Claim 1 of US 6,972,010 also recites wherein the delivery system comprises an alcohol or ester derivative of the following formulae:

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Thus, the instant ester derivatives are fairly taught in US 6,972,010. The article and agent are not described in the claim language. The Examiner notes that: MPEP § 804 (II) states, "When considering whether the invention defined in a claim of an application would have been an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. *General Foods Corp.*

v. Studiengesellschaft Kohle mbH, 972 F.2d 1272, 1279, 23 USPQ2d 1839, 1846 (Fed. Cir. 1992). This does not mean that one is precluded from all use of the patent disclosure. (*emphasis added*). "Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970)."

Therefore, the Examiner looked to the specification for guidance on the type of agent and type of article. The article is described as being panty liners, for example, with topsheets and backsheets fully discussed (Column 25, line 1 through column 33, line 57). The agent is disclosed as being derivatives of ketals, carboxamides, cyclohexanol, cyclohexyl as well as a number of oils such as peppermint oil that can convey a perception, freshness sensation, to the wearer (Column 7, line 13 and 46 through column 14, line 60). One of ordinary skill in the art would have recognized the obvious variation of the instant invention over US 6,972,010 due to the overlap in claimed subject matter as described above.

II. Claims 10-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-6 and 8-13 of copending Application No. 11/106,402. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter is embraced by the subject matter of the copending application. The copending application claims an absorbent article, such as a panty liner, comprising an agent able to convey a

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perception to the wearer wherein the agent is a cooling agent selected from the group consisting of ketals, carboxamides, cyclohexyl derivatives, etc....(Claims 2-5). The article comprises a delivery system which is an emollient containing composition comprises from about 0.1% to about 99.9% by weight of the agent and from about 99.1% to about 0.1% by weight of the emollient and the delivery system comprises triethyl citrate (claims 8-11). The article comprises a topsheet (claims 12-13). The article comprises menthol as a first cooling agent in combination with a second cooling agent (Claim 6). One of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending claims due to the overlap in subject matter as described above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

III. Claims 10-15, 18 and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 6-10, 13, and 14 of copending Application No. 10/687,897. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of the instant invention is embraced by the subject matter of the copending application. Copending claim 1 is drawn to an article comprising a cooling agent able to convey a freshness sensation to the wearer. Copending claims 2-4 are drawn to a cooling agent selected from the group consisting of ketals, carboxamides etc... and is preferably menthyl lactate. Copending claims 6-10 recites the article further comprising a delivery system wherein the delivery system is an emollient containing

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system comprising from about 0.1% to about 99.9% by weight of the cooling agent and from about 99.1% to about 0.1% by weight of the emollient and the delivery system comprises triethyl citrate. Copending claims 13 and 14 are drawn to an article such as clothing, bandage, panty liner etc... and is a hygienic absorbent article comprising a topsheet. One of ordinary skill in the art would have recognized the obvious variation of the instant invention over the copending claims due to the overlap in subject matter as described above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

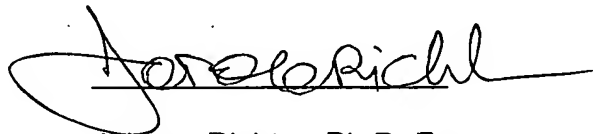
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
Art Unit 1616

A handwritten signature in black ink, appearing to read "Johann Richter", with a large, stylized loop at the beginning.

Johann Richter, Ph.D. Esq.
Supervisory Patent Examiner
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